UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFFTY AND POLLUTION PREVENTION

JUL 1 1 2013

Sherry D. Heins Bayer CropScience LP Biologics 1540 Drew Avenue Davis, CA 95618

> Subject: Notification of Minor Label Changes per PRN 98-10 Product Name: Serenade Garden Disease Control Ready To Use

EPA Reg. No: 264-1154

Your Submission Dated March 7, 2013

Dear Ms. Heins:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under Pesticide Registration Notice (PRN) 98-10, as referenced above. A screen of this request has been conducted for applicability under PRN 98-10, and it has been determined that the action request falls within the scope of this document. Our records have been duly noted, and the product label submitted with this application has been stamped "Notification Accepted" and will be placed in our records as current and updated.

Administrative review of the subject label, however, has identified certain deficiencies and label elements requiring revision in order to align its text with current label guidance (e.g., the Label Review Manual and relevant PRNs). On or before August 13, 2013, you must submit an application to amend EPA Reg. No. 264-1154 by revising the label text as directed below

Use of a "booklet" is reported in fields III 5. and 6. of the EPA Form 8570-1, dated March 7, 2013. Please confirm if the label for all reported container sizes (20, 24, 28 and 32 fluid ounces), is a peel-back accordion-type that is affixed to the container. Detachable booklets are

	I	bermissible, b	ut th	eir t	ise ma	ay trigger add	itienaclahala	or labeling	language rev	isions, such as	S
SYMBOL		ne addition of	refe	rral	state	ments and/or	the adoption o	f the Master I	abel/sublabel	format.	
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DATE		7/11/13	1	Tul	13	,		***************************************	***************************************	****************	
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EPA Form 1320-1A (1/90)

On page two, please use "and" (lower case) between "medical" and "transporatation."

To align with recent amendments to other Bayer CropScience LP products, such as EPA Reg. No. 264-1151, new "Directions for Use" text prohibiting isolation, deformulation and/or culturing of this product may be added to the label.

To align with the formatting of a recently amended Bayer CropScience LP product (EPA Reg. No. 264-1151), the page three heading "General Use Information" may be changed to "Basic Use Information." Revise the text of this section by omitting the word, "recommended." Also in this section, please replace, "It may be used…" with "It is for use…" Because this is a home/garden use product, also remove the optional text referring to "commercial landscapes" and "commercial interiorscapes."

Under the optional "Quick Facts" section, enter the actual toll-free number, if it has been determined.

In the last paragraph on page three, please replace, "may be used..." with, "is for use..."

Consider if the use sites listed for home and garden on page four should include the crops hops, peanuts and tobacco. These typically are field-grown crops.

Ensure that the container sizes (20, 24, 28 and 32 fluid ounces) reported on the EPA Form 8570-1 and draft label associated with the amendment application are adequate for use on all listed use sites (such as trees, which may be standard-size, large plants).

English Ivy is listed under the optional "Tropical Foliage" heading on page 5. The plant is not tropical and may be more accurately included by amending one of the optional headings to include "vines." Alternatively, like a recent amendment to EPA Reg. No. 264-1151, the optional "Tropical Foliage" heading may be changed to "Foliage."

To align with a similar amendment to EPA Reg. No. 264-1151, please replace the page five phrase, "To assure that the plants to be..., apply..." to become, "To test plants to be treated for potential sensitivity, apply..."

On page seven, please remove "...may be used..." from the optional text and replace the phrase with, "...is for use..."

Consider deleting "Orchard grass" from under the page seven heading "Lawns, Turf and Ornamental Turf," as the species typically is grown as forage. Also on page seven, correct the typographical error in the optional word, "disease."

As appropriate throughout the text, and to align with recent amendments to other similar Bayer CropScience LP products, replace "diseases" with either, "listed diseases" or, "diseases as listed."

Should you have any questions regarding this letter, you may contact Ms. Greenway at (703) 308-8263, or via email at greenway.denise@epa.gov

Sincerely,

Kimberly Nesci, Chief Microbial Pesticides Branch Biopesticides and Pollution Prevention Division (7511P)

DGreenway/308-8263/7-11-13/264-1154 notif OK amndmt req lttr

Serenade[®] Garden Disease Control Ready to Use

[Alternate Names for Turf Label when sold for hose-end sprayers:]

[Serenade Garden Lawn Disease Control – Ready to Use] [Serenade Garden Turf Disease Control – Ready to Use] [Serenade Garden Disease Control for Lawns - Ready to Use] [Serenade Garden Disease Control for Turf - Ready to Use]

[Optional/Alternate Statements:]

[For Home and Garden Use]
[For Home, Garden and Lawn (Turf) Use]

[Optional/Alternate Statements:]

["NOP Logo: For Organic Gardening"]

["NOP Logo: Can Be Used for Organic Gardening"]

["NOP Logo: For Organic Lawn Care"]

[Optional Claims:]

[Attacks over 40 diseases]

[Attacks both fungal & bacterial diseases]

[Apply any time of day]

[Will not burn or injure [leaves] [lawns] [(turf)] [sod]]

[Fungicide (or Biofungicide) that attacks harmful garden and lawn diseases]

[[For] Use on Roses, Vegetables, Fruits, Flowering Plants, Trees, Shrubs and Lawns (Turf) [Sod]]

[Controls Bacterial Spot, Black Spot of Rose [or Black Spot], Powdery Mildew, Rust, Gray Mold, Leaf Blight, Scab] [and other listed diseases]

[Same active ingredient used by farmers]

[Effectively controls or prevents a wide range of fungal and bacterial plant diseases]

[Promotes healthier gardens]

[Prevents and controls harmful garden diseases]

[Powered by BAYER CropScience]

[Optional Claims for Lawn and Turf Label:]

[Prevents and controls harmful (major) lawn diseases (including Brown Patch, Dollar Spot)]

[Controls Brown Patch, Dollar Spot and other listed common lawn diseases]

[Use anytime on all lawns to prevent and control major lawn diseases]

[Promotes healthy disease-free lawns]

[Same active ingredient used on golf courses]

[Promotes Greener, Healthier Lawns]

[Promotes greener, healthy disease-free lawns]

[Easy to use]

[Powered by BAYER CropScience]

Notification Accepted

Date: 7/11/2013

Reviewer: D. Green way

ACTIVE INGREDIENT:	
QST 713 strain of Bacillus subtilis*	0.074%
OTHER INGREDIENTS	. <u>99.926%</u>
TOTAL	100.000%

^{*}Contains a minimum of 1 x 108 CFU/g

EPA Reg No. 264-1154

EPA Establishment No.

KEEP OUT OF REACH OF CHILDREN CAUTION

[MEDICAL And TRANSPORTATION Emergencies ONLY Call 24 Hours A Day 1-800-334-7577 For PRODUCT USE Information Call 1-800-331-2867]

	FIRST AID
IF INHALED:	 Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

In case of emergency call toll free the Bayer CropScience Emergency Response Telephone No. 1-800-334-7577. Have a product container or label with you when calling a poison control center or doctor, or going for treatment.

[For smaller container sizes:]

[See attached booklet for First Aid Statements, Precautionary Statements, Storage and Disposal Instructions and Directions for Use.]

[Peel back tab for First Aid and Precautionary Statements and Directions for Use.]

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS CAUTION

Harmful if inhaled. Avoid breathing spray mist. Remove and wash contaminated clothing before reuse. As a general precaution, when exposed to a living microbial product such as this, wear a dust particle mask when applying this product.

ENVIRONMENTAL HAZARDS

To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

GENERAL USE INFORMATION

Serenade Garden Disease Control Ready To Use (RTU) [This product] [Alternate Statement: is a broad spectrum, preventative biofungicide recommended for the control or suppression of many important plant diseases.] [Alternate Statement: effectively controls or prevents a wide range of important fungal and bacterial plant diseases.] [Serenade Garden Disease Control Ready To Use] It may be used on roses, vegetables, fruits, nuts, flowers, houseplants, foliage, trees, shrubs, lawns, turf, sod, and ornamental turf [located in residential landscapes] [located in residential greenhouses] [located in commercial landscapes] [located in commercial interiorscapes].

[QUICK FACTS]
[For questions or comments, call toll free 1-XXX-XXXX]
[READ THE LABEL FIRST!]
[READ LABEL FIRST graphic]

WHEN TO USE

For best results, treat prior to foliar disease development or at the first sign of foliar disease infection.

[OPTIONAL Section: FOR BEST RESULTS

- Shake Well Before Use.
- · Spray to ensure thorough coverage.]

HOW TO USE [Alternate statement: APPLICATION INSTRUCTIONS]

- Shake well before using.
- Spray leaves, stems and new shoots to runoff providing complete coverage of the entire plant.
- For best results, treat prior to foliar disease development or at the first sign of foliar disease infection.
- Repeat at 7-day intervals or as needed.
- [Under conditions of high disease pressure,] When environmental conditions favor rapid disease development (high humidity, excessive rain, extreme moisture condition, etc.), spray more often [Alternate: shorten the spray interval].
- Do not water foliage within 4 hours of application.
- · Do not allow spray to drift from application site.
- [[This product] Serenade Garden Disease Control Ready To Use may be applied any time of day, in full sun and high temperatures, without stressing or burning foliage.]
- [Serenade Garden Disease Control Ready To Use can be applied up to and including the day of harvest.]

[ALTERNATE STATEMENT: WHERE TO USE: VEGETABLES, FRUITS, NUTS, ORNAMENTALS, TREES, SHRUBS, FOLIAGE, FLOWERS, FLOWERING PLANTS, AND TROPICAL PLANTS]

[ALTERNATE STATEMENT: USE SITES: VEGETABLES, FRUITS, NUTS, ORNAMENTALS, TREES, SHRUBS, FOLIAGE, FLOWERS, FLOWERING PLANTS, AND TROPICAL PLANTS.]

[SERENADE GARDEN DISEASE CONTROL READY TO USE] MAY BE USED ON [THE FOLLOWING]: [Alternate: VEGETABLES, FRUITS, NUTS, ORNAMENTALS, TREES, SHRUBS, FOLIAGE, FLOWERS, FLOWERING PLANTS, AND TROPICAL PLANTS] [Alternate: PLANTS, CROPS, SITES]

[HOME and GARDEN] [[VEGETABLE[S], FRUIT[S] AND NUT[S]] PLANTS:]

[Artichoke, Asparagus

Berries (Blueberry, Blackberry, Raspberry, Loganberry, Huckleberry, Cranberry, Gooseberry, Elderberry, Currant, Caneberry, and other berry crops)

Brassica (Broccoli, Cabbage, Cauliflower, Brussels Sprouts, Collards, Kale, Mustard Greens, Kohlrabi, and other brassica crops)

Bulb Vegetables (Onion, Garlic, Shallots, and other bulb vegetables)

Citrus (Orange, Grapefruit, Lemon, Tangerine, Tangelo, Pummelo, and other citrus crops)

Cucurbits (Cucumber, Cantaloupe, Melon, Muskmelon, Squash, Watermelon, and other cucurbit crops)

Fruiting Vegetables (Pepper, Tomato, Eggplant, and other fruiting vegetables)

Grape, Herbs/ Spices, and Hops

Leafy Vegetables (Lettuce, Celery, Spinach, Parsley, Radicchio, and other leafy vegetable crops)

Legumes/Vegetables (Beans, Green Beans, Snap Beans, Shell Beans, Dry Beans, Garbanzo Beans, Lima Beans, Peas, Chick Peas, Split Peas, Lentils, and other legume/vegetable crops)

Mango, Mint, Olive, Papaya, and Peanuts

Pome Fruit (Apple, Crabapple, Pear, Quince, Mayhaw, and other pome fruit)

Root /Tuber (Carrot, Potato, Sweet Potato, Beets, Ginger, Horseradish, Radish, Ginseng, Turnip, and other root/tuber crops)

Stone Fruit (Apricot, Cherry, Nectarine, Peach, Plum, Prune, and other stone fruit crops)

Strawberry, Sweet Corn, Tobacco, Watercress

Tree Nut (Almond, Pistachio, Pecan, Walnut, Filberts, Chestnut, Cashew, Beechnut, Butternut, and other tree nut crops)]

[RESIDENTIAL] [GREENHOUSE PLANTS:]

[Brassica (Broccoli, Cabbage, Cauliflower, Brussels Sprouts, Collards, Kale, Mustard Greens, Kohlrabi, and other brassica crops)

Bulb Vegetables (Onion, Garlic, Shallots, and other bulb vegetables)

Cucurbits (Cucumber, Cantaloupe, Melon, Muskmelon, Squash, Watermelon, and other cucurbits)

Fruiting Vegetables (Pepper, Tomato, Eggplant, and other fruiting vegetables)

Herbs/ Spices

Leafy Vegetables (Lettuce, Celery, Spinach, Parsley, Radicchio, and other leafy vegetables)

Root / Tuber (Carrot, Potato, Sweet Potato, Beets, Ginger, Horseradish, Radish, Ginseng, Turnip, and other root/tuber crops)

Strawberry]

[ORNAMENTALS, TREES, SHRUBS, FOLIAGE, FLOWERS, FLOWERING PLANTS, TROPICAL PLANTS:]

[Roses]

[Other <u>Ornamentals, Trees, Shrubs, Foliage, Flowers, Flowering Plants, Tropical Plants</u> including any or all of the plants listed as evaluated for phytotoxicity as shown below:]

[PLANTS EVALUATED FOR PHYTOTOXICITY]

[Annual and Perennial Flowering Plants:]

[Alyssum Asters Begonia Calla Lily Chrysanthemum Cyclamen Dianthus Dwarf Bee-Balm Easter Lily Garden Phlox Geraniums Gerbera Golden Star Hydrangea **Impatiens** Kalanchoe Linaria Lisianthus Lobelia Marigolds Orchids **Pansies** Petunia Poinsettia Portulaca Ranunculus Roses Salvia spp. Snapdragons Stock Verbena spp. Vinca Violas Zinnias]

[Tropical Foliage:]

[Aglaonema Dracaena spp. Hibiscus Dieffenbachia English Ivy Leatherleaf Fern

Spathiphyllum]

[Trees and Shrubs:]

[Azalea Crape Myrtle Gumbo Azalea Japanese Maple Boxwood Dogwood Indian Hawthorn Ligustrum japonicum

Lilac Photinia Rosaceae spp. Spirea.] Loropetalum Rhododendron Soft Touch Holly

[ORNAMENTALS, TREES, SHRUBS, FOLIAGE, FLOWERS, FLOWERING PLANTS, TROPICAL PLANTS:]

[Optional Statement: Some pesticides can cause phytotoxic effects ranging from slight burning or browning of leaves to distorted leaves, fruit, flowers or stems. Damage symptoms may vary with the type of plant that has been treated. It is impossible to test all plants for phytotoxicity. To assure that the plants to be treated are not sensitive to the treatment, apply a small amount of the product to a few leaves or the above ground portion of a plant and check within 3 days for signs of phytotoxicity. Use product according to label directions.]

DISEASES CONTROLLED [OR SUPPRESSED] [OR PREVENTED] [BY SERENADE GARDEN DISEASE CONTROL READY TO USE] [ON VEGETABLES, FRUIT, NUTS, AND ORNAMENTAL PLANTS] [FLOWERS, FOLIAGE, TREES, AND SHRUBS]. [Alternate: [ON PLANTS,] [CROPS,] [SITES] [:]

Anthracnose [(Colletotrichum spp.)] Bacteria [(Erwinia spp., Pseudomonas spp., Xanthomonas spp.)] Bacterial Leaf Blight [(Xanthomonas campestris)] Bacterial Speck [(Pseudomonas syringae pv. Tomato)] Bacterial Spot [(Xanthomonas spp.)] - suppression Bean Rust [(Uromyces appendiculatus)] - suppression Black Mold [(Alternaria alternata)] Black Root Rot/Black Crown Rot [(Alternaria spp.)] Black Spot of Rose [or Black Spot] [(Diplocarpon rosea)] Botrytis [(Botrytis spp.)] Botrytis Leaf Blight [(Botrytis squamosa)] Botrytis Neck Rot [(Botrytis spp.)] Downy Mildew [(Bremia lactucae, Peronospora spp., and Plasmopara viticola)] - suppression Early Blight [(Alternaria solani)] - suppression Fire Blight [(Erwinia amylovora)] - suppression Gray Mold [(Botrytis cinerea)] Greasy Spot [(Mycosphaerella citri)] - suppression Late Blight [(Phytophthora infestans)] - suppression Leaf Spots [(Alternaria spp., Cercospora spp., Entomosporium spp., Helminthsporium spp., Myrothecium spp., Septoria spp.)] Onion Downy Mildew [(Peronospora destructor)] Onion Purple Blotch [(Alternaria porri)] Phytophthora spp. Pin Rot [(Alternaria/Xanthomonas complex)] - suppression Powdery Mildew [(Uncinula necator, Erysiphe spp., Sphaerotheca spp., Oidiopsis taurica, Leveillula taurica, Podosphaera leucotricha, , Oidium spp., Podosphaera spp.)] Rust [(Puccinia spp.)] Scab [(Venturia spp.)] - suppression Sclerotinia Head and Leaf Drop [(Sclerotinia spp.)] Sour Rot

Target Spot [(Corynespora cassiicola)]

Walnut Blight [(Xanthomonas campestris)]

White Mold [(Sclerotinia sclerotiorum)] - suppression

[SERENADE GARDEN DISEASE CONTROL READY TO USE] MAY BE USED ON LAWNS, TURF [SOD], AND ORNAMENTAL TURF]:

LAWNS, TURF [, SOD] AND ORNAMENTAL TURF:

Bluegrass, Bentgrass, Bermudagrass, Dichondra, Fescue,

Orchard grass, Poa Annua, St. Augustine, Ryegrass, Zoysia, Mixtures and other grasses, or ornamental turf.

DISEASES CONTROLLED [OR SUPPRESSED] [OR PREVENTED] [BY SERENADE GARDEN DISEAS CONTROL READY TO USE] [ON LAWNS, TURF [SOD], AND ORNAMENTAL TURF]:

Lawn and Turf Diseases:

Brown Patch [(Rhizoctonia solani)]
Dollar Spot [(Lanzia spp., Moellerodiscus spp., formerly Sclerotinia homeocarpa)]
Powdery Mildew [(Erysiphe graminis)]
Rust [(Puccinia spp.)]
Anthracnose [(Colletotrichum graminicola)]
Red Thread [(Laetisaria fuciformis)]

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Store in original container only. [Alternate: in an area inaccessible to children] [or Alternate: out of reach of children]. Keep container closed when not in use. Store at room temperature.

PESTICIDE DISPOSAL AND CONTAINER HANDLING:

Nonrefillable container. Do not reuse or refill this container

If empty:. Place in trash or offer for recycling, if available.

If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

[batch codes are sticker applied to the front panel of every label on every product container]

IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness, plant injury, other property damage, as well as other unintended consequences may result because of factors beyond the control of Bayer CropScience LP. Those factors include, but are not limited to, weather conditions, presence of other materials or the manner of use or application. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE LP MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Bayer CropScience LP is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE LP DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT BAYER CROPSCIENCE LP'S ELECTION, THE REPLACEMENT OF PRODUCT.

[Money Back Guarantee: If you are not satisfied with this product, we will gladly refund your original purchase price.]

Net contents: [20 fluid ounces OR 24 fluid ounces OR 28 fluid ounces OR 32 fluid ounces]



PRODUCED FOR



Bayer CropScience LP P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, North Carolina 27709 1-866-99BAYER (1-866-992-2937)

Serenade® Garden Disease Control Ready to Use (PENDING) 03/07/2013